REMARKS

Claims 1, 10 and 25-32 are currently pending. Claim 1 has been amended to recite "wherein the polypeptide can detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B in a sample." As described in further detail below, support for this amendment is found throughout the specification as filed, in particular, in the specification at page 2, lines 24-25, and in originally filed claims 1 and 12, and therefore the amendment is not new matter. Entry of these amendments is thus respectfully requested.

I. Rejections under 35 U.S.C. § 112, First Paragraph (New Matter)

Claim 1 and claims dependent therefrom have been rejected for allegedly containing subject matter which is not described in the specification such as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention as of the time of filing. Specifically, the Examiner states that while there is sufficient support in the specification for claims limited to polypeptides having at least one antigenic determinant that "can raise antibodies," there is no descriptive support in the specification for a polypeptide having at least one antigenic determinant which "elicits an immune response," as this encompasses both humoral and cell-mediated responses.

Applicants traverse the rejection and its supporting remarks. However, Applicants respectfully assert that the rejection is moot in view of the presently pending claims, which are drawn to polypeptides "wherein the polypeptide can detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B in a sample." As noted above, support for these amended claims is found throughout the specification as filed, in particular, in the specification at page 2, lines 24-25, and in the below originally filed claims.

> 1. A fragment of a protein disclosed in WO99/36544, wherein the fragment comprise at least one antigenic determinant.
>
> 12. The use of the fragment of claim 1, claim 2 or claim 3, the polypeptide of claim 5, the protein of claim 8,

> the antibody of claim 7, and/or the nucleic acid of claim 9, in the manufacture of (i) a medicament for treating or preventing infection due to Neisserial bacteria (ii) a ***diagnostic reagent for detecting the presence*** of Neisserial bacteria or ***of antibodies raised against Neisserial bacteria*** and/or (iii) a reagent which can raise antibodies against Neisserial bacteria.

The originally filed claims are part of the specification and therefore can provide written description support for the presently filed claims. Original claim 12 is directed to use of polypeptide fragments of the *Neisseria meningitidis* serogroup B proteins disclosed in WO99/36544 to detect the presence of antibodies raised against Neisserial bacteria.

As such, support for the presently pending claims is found in the originally filed specification in a way such that one skilled in the art would have recognized that the inventor had possession of the claimed invention as of the time of filing. Thus the presently pending claims do not include new matter. Applicants therefore respectfully request withdrawal of the rejection.

II. Rejection under 35 U.S.C. § 112, First Paragraph (Strain Deposit)

Claims 1, 10 and 25-32 have been rejected for an alleged failure to provide adequate written description and enabling disclosure on the grounds that the specification does not provide evidence that the claimed biological material, *Neisserial meningitidis* strain B, is (1) known and readily available to the public; (2) reproducible from the written description, *e.g.*, sequenced; or (3) deposited.

Applicants respectfully traverse the rejection and its supporting remarks. One of skill in the art would readily recognize that "*Neisserial meningitidis* strain B" refers to "*Neisseria meningitidis* serogroup B," a biological material which is readily available to the public. Nevertheless, in the interests of expediting prosecution, Applicants have amended claim 1 to recite "*Neisseria meningitidis* serogroup B." Applicants thus respectfully request withdrawal of the rejection.

III. Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1, 10 and 25-32 continue to be rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to enable a polypeptide having a length of 100 amino acids or less and comprising a contiguous amino acid sequence with "at least 70% sequence identity to SEQ ID NO: 1331," where the polypeptide comprises at least one antigenic determinant "that elicits an immune response against *Neisserial meningitidis* strain B."

Applicants continue to traverse the rejection and its supporting remarks. However, in the interests of expediting prosecution, Applicants have amended the claims to recite a polypeptide "wherein the polypeptide can detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B in a sample." Applicants respectfully submit that these presently pending claims are enabled. The Examiner has acknowledged that, "[a]pplicants are correct that the quantity of experimentation is not undue for the routine synthesis of peptides and its screening with 114-1 polyclonal antibody." See first paragraph of page 7 of the Office Action dated June 16, 2006. All that is required to make and use polypeptides within the scope of the pending claims is to synthesize polypeptides and screen with 114-1 polyclonal antibodies, which the Examiner has agreed would not require undue experimentation. Polypeptides that are bound by a 114-1 polyclonal antibody mixture would detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B. Since making and using polypeptides commensurate in scope with the pending claims would not require undue experimentation, the applicants have enabled the pending claims.

The specification as filed provides ample guidance regarding how to make and use the presently claimed polypeptides. Guidance regarding the preferred sequences of such polypeptides is provided, for example, at page 2, lines 10-13, which describes how to identify sequences falling within the requisite sequence identity limitations; pages 64-71, which lists other predicted antigenic fragments of 114-1 (the full-length protein from which SEQ ID NO: 1331 is derived); and page 37, lines 9-29, which describes methods for identifying antigenic polypeptides. Further, the specification also provides general guidance to those of skill in the art regarding how to make the claimed polypeptides. For example, the specification describes how to make the polypeptides by recombinant expression or chemical synthesis. See, e.g., page 2, lines 18-22, and page 5, line 21

through page 21, line 3. To make the claimed invention, one of skill need only synthesize a set of peptide fragments having the claimed sequence identity and length limitations, the sequence of which may be selected using the disclosed methods for identifying antigenic polypeptides and guided by the other predicted antigenic fragments of 114-1 listed in the specification. Such synthesis was so routine as of the priority date of the present application that one of skill in the art could order such purified polypeptides from a company. Then the person of ordinary skill in the art need merely screen the peptides for binding to any antibody known in the art as a *Neisseria meningitidis* serogroup B antibody. Such screening involves the use of routine immunoassay methods well known to those of skill in the art. If there is a detectable interaction between the synthesized peptide and the requisite antibody, then the synthesized peptide is within the scope of the claimed invention.

Thus it would not require undue experimentation to make and use the presently claimed invention and therefore the claimed invention is enabled. As such, Applicants respectfully request that the Examiner withdraw the rejection of the claims for lack of enablement.

IV. Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1, 10 and 25-52 have been rejected as being indefinite. The Office Action states that claim 1 is vague, indefinite and/or incorrect in the recitation *"Neisserial" meningitidis* because the art recognizes *Neisseria meningitidis* bacterium, not *Neisserial meningitidis* and further, that it is unclear whether "strain B" refers to *N. meningitidis* of any serogroup or just serogroup B. Applicants have amended the claims to recite "*Neisseria meningitidis* serogroup B." In view of these amendments, Applicants respectfully assert that the pending rejections are moot and request withdrawal of the rejections.

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CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 223002100200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 13, 2006

Respectfully submitted,

By _____

Otis Littlefield
Registration No.: 48,751
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
(415) 268-6846